

BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP

www.bartlit-beck.com

CHICAGO OFFICE
COURTHOUSE PLACE
54 WEST HUBBARD STREET
CHICAGO, IL 60654
TELEPHONE: (312) 494-4400
FACSIMILE: (312) 494-4440

June 21, 2013

DENVER OFFICE
1899 WYNKOOP STREET
8TH FLOOR
DENVER, CO 80202
TELEPHONE: (303) 592-3100
FACSIMILE: (303) 592-3140

Michael E. Gans
Clerk of the Court
United States Court of Appeals for the Eighth Circuit
Thomas F. Eagleton U.S. Courthouse
111 South 10th Street
St. Louis, Missouri 63102

WRITER'S DIRECT DIAL:
(312) 494-4473
adam.hoeflich@bartlit-beck.com

Re: *United States ex rel. Laurie Simpson v. Bayer Healthcare et al.*,
No. 12-2979: Response to Appellant's 28(j) Letter

Dear Mr. Gans,

Pursuant to Federal Rule of Appellate Procedure 28(j), Appellees respectfully respond to Appellant's June 19th letter regarding the United States' Statement of Interest in *United States ex rel. Simpson v. Bayer Corporation*, No. 05-3895 (D.N.J.).

Yet again, Appellant alerts this Court to the Government's arguments in another case, involving different alleged conduct and legal theories. And yet again, the Statement is irrelevant to the question here of whether Appellant's allegations satisfy Rules 8 and 9(b).

For example, Appellant highlights the Government's discussion of claims that are not "legally reimbursable," but that discussion addresses allegations in that case of statutory ineligibility under 42 U.S.C. § 1395y(a)(1)(A). Ex. 2 at 3-5. Appellant has no such allegations here. Likewise, the Government's position that a defendant may face liability for knowingly submitting non-reimbursable claims, *id.* at 3 n.1, is inapposite here because Appellant has not alleged with particularity that any claim was non-reimbursable. *See* Appellees' Br. 29-36. And, the Government's position that a violation of the Anti-Kickback Statute means "all claims tainted by those kickbacks are false," Ex. 2 at 5, is irrelevant because here Appellant has not alleged any nexus between kickback payments and claims, let alone provided particular allegations regarding which claims she believes were tainted.

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As for representative false claims, the Statement does not address the Eighth Circuit precedent that governs this case. Ex. 2 at 8-9. This precedent has been fully briefed and argued and, as Bayer has demonstrated, Appellant's allegations even fail the "reliable indicia" standard adopted by other courts. *See Appellees' Br.* 37-48.

Finally, unrelated to the Government's Statement, Appellant asserts that she can plead materiality by alleging that it is "plausible" the government would consider alleged mismarketing in deciding to pay a claim. That is incorrect. The Rule 8 requirement that a claim be "'plausible on its face'" does not authorize speculative pleading about what the government might have done. This is a fraud case, and Simpson must plead materiality with particularity under Rule 9(b), *United States ex rel. Vigil v. Nelnet*, 639 F.3d 791, 796 (8th Cir. 2011).

Accordingly, the Court should affirm.

Very truly yours,



Adam L. Hoeflich

Counsel for Appellees

cc: Edward Normand, Esq. (via ECF)

Attorney for Relator-Appellant